RFP NO.:	NIMH-01-DI-0017
TITLE:	"Collaborative Research Pertaining to NIMH's Mood & Anxiety Disorders Program (NIMH: MAP)"
OMB No.:	0990-0115
ISSUED BY:	Robert D. Barnie Contracting Officer National Institute of Mental Health Contracts Management Branch 6001 Exec. Blvd., Rm. 6107, MSC 9603 Bethesda, MD 20892-8030 Voice: 301-443-4116 Fax: 301-443-0501 Email: rb245s@nih.gov Collect calls will not be accepted
DATE ISSUED:	June 20, 2001
DATE DUE:	July 20, 2001, 3:30 pm Eastern Time
PURCHASE AUTHORITY:	Public Law 95-128 as amended
SMALL BUSINESS SET-ASIDE:	No, NAICS Code 621420
JUST IN TIME:	Yes
OFFER EXPIRATION DATE:	Offers will be valid for 120 days unless a different period is specified by the offeror.

NOTE: OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE NIMH WEBSITE AT http://www.nimh.nih.gov/grants/indexcon.cfm AND/OR FEDBIZOPPS AT http://www.fedbizopps.gov/ FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Dear Sir/Madam:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-01-DI-0017. Proposals are being solicited under Full and Open Competitive procedures.

It is expected that one (1) cost-reimbursement, completion contract will be awarded on or about September 30, 2001, with a base period of five (5) years and one (1) 5-year option.

The RFP does not commit the Government to pay costs for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with any acquisition action.

SPECIAL ATTENTION SHOULD BE DIRECTED TO THE TECHNICAL PROPOSAL INSTRUCTIONS & BUSINESS PROPOSAL INSTRUCTIONS CONTAINED IN ATTACHMENT 4. Your attention is further directed to the "Proposal Intent Response Sheet" contained in ATTACHMENT 5. Please complete this form and return it to this office via mail, fax or email on or before July 9, 2001. This will allow NIMH to expedite preparations for the technical review of proposals.

The documents included with this electronic RFP package are as follows:

I. Streamlined RFP

   A. Statement of Work (SOW) (Attachment 1)
   B. Deliverables and Reporting Requirements (Attachment 2)
   C. Evaluation Factors for Contract Award (Attachment 3)

II. Specific RFP Instructions, Conditions and Notices to Offerors (Attachment 4)

III. Proposal Intent Response Sheet (Attachment 5)

IV. Applicable RFP References (Attachment 6)

   A. General Clauses and Provisions
   B. Forms, Formats and Attachments
   C. Uniform Contract Format (sample contract clauses Section B-H)

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition.

Your proposal must be signed by an official authorized to contractually bind your organization and must indicate that it is valid for a period of at least 120 days. One (1) original and ten (10) copies of your technical proposal and one (1) original and five (5) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN 3:30 P.M., LOCAL PREVAILING TIME ON July 20, 2001, at one of the following addresses:

If hand-delivered or delivery service

Contracting Officer
National Institute of Mental Health
Contracts Management Branch
6001 Exec. Blvd., Rm. 6107, MSC 9603
Rockville, MD 20852-9603

If using U.S. Postal Service

Contracting Officer
National Institute of Mental Health
Contracts Management Branch
6001 Exec. Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603

Questions concerning any areas of uncertainty, which in your opinion, require clarification or correction, must be furnished in writing (Fax or e-mail is also acceptable) to Robert D. Barnie, and marked "Offeror's Questions, RFP No. NIMH-01-DI-0017".

ANY DISCUSSION OF THIS RFP WITH ANY INDIVIDUAL(S) OUTSIDE THE CONTRACTS MANAGEMENT BRANCH, NIMH, MAY RESULT IN DISQUALIFICATION OF THE OFFEROR AND REJECTION OF ANY PROPOSAL SUBMITTED.

Sincerely,

/s/

Robert D. Barnie, Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health, NIH

Attachments: 1-6

ATTACHMENT 1 to STREAMLINED RFP No. NIMH-01-DI-0017

Statement of Work

Title: "Collaborative Research Pertaining to NIMH's Mood and Anxiety Disorders Program (NIMH: MAP)"

Background:

Obtaining cultural diversity in research subject populations is a congressional mandate. Minority inclusion in Federally funded research is specifically prescribed in *"The NIH Revitalization Act of 1993"* (Section 492B of Public Law 103-43).

The National Institute of Mental Health (NIMH) seeks to expand minority research inclusion by supporting, promoting and augmenting the ability of minorities with serious mental illnesses to participate in federally funded NIMH Intramural research projects. A first step in expeditiously achieving these goals is to develop a contract with a local medical facility (preferably a university with a medical school and department of psychiatry) that is located in close proximity to NIMH, Bethesda, MD, and has good access to a significant number of minority patients.

Cultural diversity in subject accrual is a critical factor in the NIMH Mood and Anxiety Disorder's Program's mission to further the understanding of the pathophysiology of mood and anxiety disorders. The development of a contract with a medical facility with access to a significant number of minority patients will enable NIMH mental health investigators to overcome some of the obstacles that hinder minority research participation in research protocols. These difficulties include inequity in access to information about and access to ongoing mental health research protocols. Research exploring the possibility of ethnic differences in the pathophysiology of psychiatric disorders is urgently needed. Study designs will include diverse populations in order to make cross-ethnic comparisons relevant to treatment choice, treatment outcome and treatment development.

In accordance with the precepts of the newly established "National Center on Minority Health and Health Disparities, this contract will provide an important initiative toward promoting, assisting, and supporting research participation in the minority community.

Examples of Types of Studies to be Performed Under this Contract:

Research protocols typical of those to be conducted under this contract will include clinical treatment trials, imaging trials for major depression, Bipolar disorder, anxiety disorder, and genetic analysis. Protocols generally will have between 20 to 100 subjects, take 1 to 5 years to complete, and involve both the NIMH IRP and the Contractor's site. Depending on the size of the protocols developed, an estimated 3 to 5 protocols will be progressing at any given year of the contract, at the contractor's facility, with subject accruals anticipated to be 125 annually including healthy volunteers and patients. Over the five year base period of the contract it is estimated that five protocols will be completed by the contractor. Examples of the types of protocols that will be written in conjunction with NIMH MAP and contractor staff include:

1. MAP will explore the relevance of specific α2-adrenergic receptor subtypes in sympathetic pathways in healthy controls and later in patients with mood and anxiety disorders. For both disorders, it is well documented that noradrenergic dysregulation plays a key role in the pathophysiology of these disorders. It has been shown that the prevalence of α2- sub receptors

differs between African Americans and Caucasians (These differences may account for the well documented increased risk for hypertension in African American population.) Potentially, these differences may be relevant to treatment choice and treatment outcome for African American patients with mental illness. A total of 120 subjects will be studied.

2. NIMH MAP efforts to elucidate the neurobiological basis of mood disorders and the mechanisms of their treatments include a proposed effort to characterize 5-HT_{1A} receptor binding potential in mood and anxiety disorders in vivo, by using highly selective ligands to compare PET measures of 5-HT_{1A} receptor binding between unmedicated Major Depressive Disorder (MDD) and Biploar Disorder (BD) samples against healthy and medical controls. A total of 90 subjects will be studied.

3. NIMH MAP projects also include an exploration into the effects of fluoxetine on attention and emotional memory in anxious and depressed youth. The project uses fMRI to examine the effects of fluoxetine on neurocognitive correlates of pediatric mood and anxiety disorders. Deficits in brain systems mediating attention bias and emotional memory in pediatric mood and anxiety will be documented. Additionally, the effects of treatment with fluoxetine on these deficits will be assessed. A total of 130 children and adolescents will be studied.

Objectives:

1. The contractor shall, in collaboration and with support from the NIMH Mood and Anxiety Disorder research staff, perform clinical investigation into the causes and treatment of serious mental illnesses in minority subjects.

2. The contractor in conjunction with NIMH MAP investigators from the Mood and Anxiety Disorders Program shall collaboratively design and conduct research protocols designed to fill critical gaps in the body of knowledge regarding the pathophysiology, causes, consequences and treatment of serious mental illness in minorities.

3. The contractor in conjunction with NIMH IRP investigators from the MAP shall identify barriers that inhibit minority patients from participating in mental health protocols. The contractor shall provide opportunities for minorities with serious mental illnesses to participate in research studies designed to enhance our understanding of the causes of these disorders and discover better treatments.

General Requirements

Independently and not as an agent of the Government, the contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below.

Specific Requirements

Specifically, the contractor shall fulfill the objectives of this contract by performing the following tasks:

TASK 1. The contractor shall provide opportunities for minorities with serious mental illness to participate in the research studies in order to enhance our body of knowledge of the causes of these disorders and increase the potential to develop better treatments. The contractor shall recruit mentally ill and healthy minority research subjects as participants in joint NIMH/Contractor clinical research protocols.

TASK 2. The contractor in collaboration with NIMH researchers shall write, design and conduct clinical research protocols designed to fill gaps in the body of knowledge regarding the pathophysiology, causes, consequences and treatment of severe mental illness in minorities. These clinical research protocols shall be designed to explore the underlying causes and potential treatments for serious mental illness in a minority subject population. Within one year of contract award the contractor shall be actively recruiting minorities with serious mental illnesses into research protocols developed. Patient recruitment, patient assessment, outpatient visits, research procedures and subsequent follow-up shall be performed at both the contractor's facility and at the NIH Clinical Center (in Bethesda, Maryland) in accordance with the terms and conditions established in the protocol and as directed by the NIMH GPO. Within two years of the contract award the contractor shall be able to demonstrate that the research effort is resulting in the generation of scientific data that enhances the body of knowledge of serious mental illness in minorities. All protocol approval will meet the guidelines of both the Contractor's human research subjects' protocols and NIMH human research subjects' protocols. All protocols shall be scientifically reviewed and approved by the Office of the Scientific Director of NIMH, the NIMH Project Officer, and approved by both the NIMH IRB and the contractor's IRBs.

Subject recruitment shall be conducted in accordance with the requirements of the protocol, as directed by the NIMH Government Project Officer (GPO), and in accordance with the following terms and conditions:

1. All tasks described in this statement of work shall be coordinated and implemented by the contractor in conjunction with and under the guidance of the GPO.

2. All research activities conducted under this contract shall follow the state-of-the-art of good clinical trial practice criteria, in order to generate data that can be published in peer-reviewed leading scientific journals.

3. All institutional, NIMH, and federal regulations concerning informed consent shall be fulfilled. Protocols and patient consent forms shall be approved by the appropriate IRBs.

4. All materials/data collected by the contractor from the specific studies funded under this contract shall be made available to NIMH electronically and/or as hard copy prior to the end of the contract period or within 30 calendar days of a written request by the GPO or the Contracting Officer (CO). The contractor shall use standard procedures to safeguard the confidentiality of research records.

5. NIMH or its designees shall have the right to audit patient records and research data, as well as independently access and analyze study data, at any time during the study.

6. The contractors Investigators, in conjunction with NIMH GPO, shall be responsible for all aspects of the performance of this contract, including the performance of any subcontracts. The contractor shall not enter into any subcontracts that have not received the scientific and technical review of the GPO and that has not been approved, in writing, by the CO.

7. No data from any studies funded under this contract shall be released, presented at meetings or published without prior review of the Mood and Anxiety Disorders Program Chief.

8. The GPO or the CO may require that the entire database, and all associated programs, source code, codebooks, indices, data tables, documentation, etc. associated with any study, be transferred within 30 calendar days, in a readily usable form to NIMH or its designee.

9. At the end of the contract period, or at the discretion of the GPO and CO, the Contractor shall be prepared to transfer to NIMH or its designee all trial material, data collection procedures, all data, and any other information, equipment, or procedures necessary to implement and conduct a study.

10. The contractor shall establish procedures to safeguard the confidentiality of any proprietary information provided by the GPO.

TASK 3. Collaborating NIMH scientists shall receive faculty (without pay) appointments at the contractor's facility according to the guidelines established by the contractor. Similarly, contractor staff faculty and fellows participating in this contract shall receive NIMH Special Volunteer appointments according to the rules and regulations established by the NIMH.

TASK 4. The contractor, in conjunction with the NIMH shall establish a Joint Steering Committee (JSC) consisting of eight members. The eight members shall be composed of 3 senior members of the contractor's staff and/or faculty and 3 senior members of the NIMH administration and/or faculty plus one co-chair from the Contractor's Institution and one co-chair from NIMH. The co-chairs will be responsible for leading the JSC. The JSC shall meet at least annually, with the first meeting being held approximately 13 months from the award date of the contract. The JSC may meet more frequently if determined to be necessary. The JSC shall review the program and provide senior level direction to the contract participants. Prior to these meetings the contractor shall prepare and submit an Annual Report to the GPO for review and approval. These Annual Reports shall include detailed progress made to date, any problems encountered, the impact of those problems, the resolution or proposed resolution to those problems, and any anticipated problems, as well as outline the protocols developed during the past year, the number of subjects recruited in each protocol, and the protocol completion rates of subjects. After the GPO has reviewed and approved the Annual Reports they shall be given to the JSC, for review prior to their annual meeting, for recommendations and suggestions. The contractor shall evaluate all recommendations and suggestions made by the JSC and implement changes with the concurrence of the GPO.

Outcome:

A successful outcome of this contract shall include:

1. NIMH scientists associated with this contract are actively collaborating with minority contractor scientists and these NIMH scientists are receiving Faculty WOC (without compensation) appointments at the contractor's site;
2. Contractor staff associated with this contract are actively collaborating with NIMH scientists and these contractor scientists are receiving NIMH Intramural positions as Special Volunteers. Contractor and NIMH staff participating in research under this contract shall hold these appointments during participation in the contract. A joint position shall terminate once an

individual's participation in the contract is complete. NIMH may unilaterally terminate the joint appointments at any time for failure to comply with contract directives.

3. Minorities with serious mental illnesses are participating in 3 to 5 NIMH MAP supported research protocols designed to enhance our understanding of the causes of these disorders so that better treatments can be developed. Subject accrual will be approximately 125 annually, including patients and healthy volunteer controls; and
4. Research designed to fill critical gaps in the body of knowledge of the pathophysiology and treatment of mental illness in minorities results in useful data.

Timing of outcome:

Year One:
Collaborations begin between NIMH and contractor staff associated with the program begin. Minorities with serious mental illnesses are being actively recruited into NIMH IRP/Contractor research studies.

At Two Years:
NIMH IRP supported contractor/NIMH collaborative research is generating scientific data that will enhance our knowledge of serious mental illness in Minorities in order to move forward and enhance the development of effective treatments and eliminate health disparities in the treatment of Minorities. Approximately 125 minority research subjects a year are being recruited into NIMH/Contractor protocols through the contractor's facility.

At Five Years:
Research designed to fill critical gaps in the body of knowledge of the pathophysiology and treatment of mental illness in minorities has resulted in useful data. NIMH/Contractor collaborative protocols have resulted in clinical research publications in peer-reviewed scientific journals.

Reporting Requirements:

Annual protocol summaries and reviews shall be submitted to the NIMH IRB according to NIMH IRP Policy.

Annual protocol summaries and reviews shall be submitted to the contractor's IRB according to contractor's IRB Policy.

The Joint Steering Committee shall meet and assess the progress and success of the program annually and determine if any changes in contract operations are necessary. The contractor shall provide a quarterly report to the GPO and the JSC detailing the program's progress; protocols, reports on subject recruitment, and protocol completion rates of subjects. This report shall be presented by the contractor's senior staff member.

The annual meeting scheduled to be held during the 5th year of contract performance shall be held at least one month prior to the contract's expiration date. The purpose of this meeting will be to complete a major review of the program.

Option

Unless the Government exercises its option pursuant to the Option Clause set forth below, the contract will consist only of years 1 through 5 of the Statement of Work. Pursuant to clause 52.217-9 set forth below, the Government may, by unilateral contract modification, permit the Contractor to perform five

(5) additional years of the Statement of Work. During this five year continuation period the Contractor shall continue to fulfill the original objectives of the contract, by functioning in the capacity of developing research protocols and increasing minority research subject accrual (125 annually).

If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in Article B.

Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 10 days; provided that the Government gives the contractor a preliminary written notice of its intent to extend at least 30 days before the contract expiration. The preliminary notice does not commit the Government to an extension.

(c) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause shall not exceed 10 years.

ATTACHMENT 2 to STREAMLINED RFP No. NIMH-01-DI-0017

DELIVERABLES AND REPORTING REQUIREMENTS

1. DELIVERIES OR PERFORMANCE

Performance of this contract shall begin on the effective date and shall not extend beyond the estimated completion date of the contract unless the period is extended by modification to the contract.

2. DELIVERY SCHEDULE

A. After the contract award date, the Contractor shall deliver the following items/reports to the GPO in accordance with the delivery schedule set forth below:

ITEM/DESCRIPTION	QUANTITY	DUE DATE
1. Quarterly Reports	2	15 days after the close of each reporting period
2. Final Developed Protocol	2	Immediately following approval
3. IRB Approved Consent Document	2	Immediately following approval
4. Annual Report for Gender/ Minority Tracking	2	15 days after each annual anniversary date
5. Annual Report	2	15 days after the close of each reporting period.
6. Final Report	2	By contract expiration date
7. Other Materials	2	As required by the GPO
8. Draft Publications	2	Before submitting for publication

B. The items/reports identified shall be addressed and delivered to the GPO in the quantities stated. An electronic copy of each Quarterly, Annual and Final Report shall also be submitted to the GPO. In addition, one (1) copy of each Quarterly, Annual Report and Final Report shall be delivered to the Contracting Officer by the specified delivery date.

C. The following FAR Clauses apply to this contract and are incorporated by reference with the same force and effect as if set forth in the full text.

FAR CLAUSE	TITLE AND DATE
52.242.15	Stop Work Order (August 1989), Alternate I (April 1984)
52.246-8	Inspection of Research and Development – Cost Reimbursement (April 1984)

ATTACHMENT 3 to STREAMLINED RFP No. NIMH-01-DI-0017

EVALUATION FACTORS FOR CONTRACT AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractor in relation to the needs of the project as set forth in the RFP. The merits of the proposal will be evaluated carefully. The proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. HUMAN SUBJECTS EVALUATION

This research project involves human subjects. NIH policy requires:

a. Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIMH that a designated exemption is appropriate.

If concerns are identified you will be afforded the opportunity to further discuss and/or clarify your position during discussions and in your Final Proposal Revision (FPR). If, after discussions, concerns still exist, your proposal may not be considered further for award.

b. Data and Safety Monitoring

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The

reviewers should refer to the Statement of Work for the solicitations specific requirements for data and safety monitoring.

The NIMH will evaluate the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis.

If the information provided about Data and Safety Monitoring is determined to be inadequate, you will be afforded the opportunity to further discuss and/or clarify your plan during discussions and in your Final Proposal Revision (FPR). If after discussions, the plan is considered inadequate, your proposal may not be considered further for award.

3. WOMEN AND MINORITIES

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for Phase III clinical trials, it is required that all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable, unless the Government has specified in the Statement of Work that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups.

Where the offeror determines that inclusion of women and minority populations is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIMH will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify, or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

4. CHILDREN

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are scientific and ethical reasons not to include them.

The offeror's proposal must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. If the offeror determines that exclusion of a specific age range of child is appropriate, the proposal must also address the rationale for such exclusion.

If the information about the inclusion of children is absent or considered inadequate, you will be afforded the opportunity to further discuss, clarify or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

5. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. The offeror shall include all information which documents and/or supports the qualification criteria in one clearly marked section of its proposal. The qualification criteria establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FRPs) by the Contracting Officer in order for your proposal to be considered any further for award.

1. The offeror must be able to demonstrate that they have a sufficient number of minority mentally ill patients and minority healthy volunteer controls to meet the requirements of the Statement of work.
2. The offeror must be located in close proximity to the NIMH, Bethesda, MD to allow for both NIMH investigators and contractor investigators, patients and controls to commute between the NIMH and contractor facilities on, at a minumum, a weekly basis.

6. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. Proposals submitted in response to this RFP will be evaluated based on the following factors, which are listed and weighted in order of their relative importance.

Evaluation Criteria	Weight
1. Understanding the Problem	35

Offeror must: 1) demonstrate a thorough understanding of the objectives of this project ; 2) have direct knowledge and hands on experience in planning, setup, recruitment and conducting a program of psychiatric research involving minorities; and 3) demonstrate the capacity to participate in collaborative research on mental illness.

2. Technical Approach	35

The offeror must document: 1) the methodology to be employed in achieving the contract objectives; 2) the adequacy of the approach proposed; 3) their ability to provide a sufficient number of minority patients and minority healthy controls and 4) a discussion of potential problems with proposed solutions.

3. Personnel	10

Demonstrated qualifications, availability, and experience of professional and technical personnel to perform the tasks of this contract as demonstrated by resumes and discussion.

4. Management Capability	10

The offeror must show: 1) management and organizational skills and plans that will provide assurance that the project milestones and goals will be met effectively and in a timely manner; 2) demonstrated capacity to collaborate with research organizations in terms of quality and timeliness and to work with researchers to maximize the usefulness of resources. The above management capability can be

demonstrated by documenting that one or more key staff members have experience with projects of similar complexity, and that milestones were appropriately set and goals were met.

5. Facilities 10

The offeror shall describe the availability and proposed utilization of appropriate facilities to successfully perform the work requirements.

7. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment t use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation.
(f) Extend of participation of SDB concerns in terms of the value of the total acquisition

8. EVALUATION OF OPTIONS

It is anticipated that the contract awarded from this solicitation will contain an option provisions and period. In accordance with FAR Clause 52.217-5, Evaluation of Options (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

ATTACHMENT 4 TO STREAMLINED RFP No. NIMH-01-DI-0017

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

A. 1. INSTRUCTIONS TO OFFERORS – COMPETITIVE ACQUISITION (FAR Clause 52.215-1 (February 2000))

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*" or "*written*" means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's

FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

B. JUST IN TIME

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the discussion process. Specifically, the travel policy, the annual financial statement, the total compensation plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy: The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their Final Proposal Revision (FPR).

Annual Report: The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a copy of their most recent annual report as a part of their final FPR.

Total Compensation Plan: The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a total compensation plans as a part of their FPR.

Subcontracting Plan: The offeror's Small Business Subcontracting Plan shall not be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit an acceptable subcontracting plan.

Cost/Pricing Information: The offeror's business proposal shall include the basic cost/pricing information specified in the BUSINESS PROPOSAL INSTRUCTIONS of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. (The information may also include the submission and certification of cost or pricing data.)

C. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 621420.

2. The small business size standard is $5 million.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation (except for foreign acquisitions), the inclusion of the North American Industry Classification Systems (NAICS)

Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

D. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

E. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 30, 2001.

It is anticipated that the award from this solicitation will be a five-year, Cost Reimbursement, Completion type contract with one-five year option period, and that incremental funding will be used.

F . COMMITMENT OF PUBLIC FUNDS

The CO is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

G . COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the CO cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

H . RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

I. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in Attachment 3 of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

J. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

K. SERVICE OF PROTEST (AUGUST 1996) – FAR 52.233-2

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the CO (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

If hand-delivered or delivery service	If using U.S. Postal Service
National Institute of Mental Health	National Institute of Mental Health
Contracts Management Branch	Contracts Management Branch
Attn: Contracting Officer	Attn: Contracting Officer
6001 Executive Boulevard	6001 Executive Boulevard,
Room 6107, MSC 9603	Room 6107, MSC 9603
Rockville, Maryland 20852	Bethesda, Maryland 20892-9603

The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

L. HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement

agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

M. GOVERNMENT NOTICE FOR HANDLING PROPOSALS

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE OF HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 352.215-1.

(a) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(b) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

2. INSTRUCTIONS TO OFFERORS

A . GENERAL INSTRUCTIONS

The following instructions will establish the acceptable minimum requirements for the format and content of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Type Contract and General Clauses**

It is contemplated that a cost-reimbursement/completion type contract will be awarded. (See General Information). Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the address in the attached solicitation cover letter, and mark each package as follows: RFP No. NIMH-01-DI-0017 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

(a) COVER SHEET

Include RFP number, title, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

(b) TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 6).

(c) BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 6).

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Attachment 5).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resource information, such as labor-hours and categories, materials, subcontracts, travel, etc, and associated cost so that the offeror's understanding of the project may be evaluated. (See Attachment 5, "Technical Proposal Cost Information"). However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided , that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Attachment 3, "Evaluation Factors for Contract Award".

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the CO determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon(as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Human Subjects**

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protection (OHPR), Office of the Secretary (OS), Department of Health and Human Services (DHHS). The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OHRP, (telephone: 301-496-7005), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OHRP and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(10) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000, at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, tilted "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/ordr/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

(11) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research"

published in the NIH Guide for Grants and Contracts on August 2, 2000 at the following web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html

A complete copy of the updated Guidelines is available at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm

The revisions relate to NIH defined Phase III clinical trials and require: a) all proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all contractors to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Attachment 3, "Evaluation Factors for Contract Award" of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See Attachment 5 of this RFP) shall be used in proposal preparation.

(12) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998, and is available at the following URL address: http://www.nih.gov/grants/guide/notice-files/not98-024.html.

Offerors may also obtain copies from the contact person listed in the RFP.

(13) **NIMH Data and Safety Monitoring in Clinical Trials**

In June 1998, the National Institutes of Health (NIH) issued a policy on data and safety monitoring (http://grants.nih.gov/grants/guide/notice-files/not98-084.html) that requires oversight and monitoring of all intervention studies to ensure the safety of participants and the validity and integrity of the data. The policy further elaborates that monitoring should be commensurate with risks and with the size and complexity of the trials. The NIH already requires data and safety monitoring, generally in the form of Data and Safety Monitoring Boards (DSMBs), for phase III clinical trials. For earlier trials (phase I and II), a DSMB may be appropriate if the studies have multiple clinical sites, are blinded (masked), and/or employ particularly high-risk interventions or vulnerable populations.

The following provides further guidance for monitoring of phase I and II trials. This guidance does not take the place of the Institutional Review Board (RB) guidelines, Food and Drug Administration (FDA) requirements, or special NIH guidelines (e.g. NIH Guidelines for Research Involving Recombinant DNA Molecules).

Monitoring Plan

For phase I and II clinical trials, investigators must submit a general description of the monitoring plan as part of the research application. This plan will be reviewed by the scientific review group and any comments or concerns will be included as an administrative note in the summary statement. In addition, before the trial begins, a detailed monitoring plan must also be included as part of the protocol, and submitted to NIMH and the local IRB. Oversight by NIMH staff must ensure that monitoring plans are in place for all phase I and II trials. At a minimum, all monitoring plans must include a description of the reporting mechanisms for serious and unexpected adverse events, as well as any other unanticipated problems involving risks to subjects or others, to the local IRB, the FDA (as appropriate), and those monitoring data and safety. Investigators must ensure that the NIMH Project Officer is informed of any actions taken by the IRB as a result of such adverse events. The decision for any NIMH action lies with the Institute Director.

The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the trial. For multi-site phase III clinical trials, NIH requires the establishment of an independent DSMB. The DSMB should be composed of experts in scientific disciplines needed to interpret the data and ensure participant safety, or have these experts available if warranted. Other requirements are detailed in the NIH policy notice cited above. If the DSMB notes serious and unexpected adverse events, or any other unanticipated problems involving risks to subjects or others, related to the study, IRBs at all sites should be notified in a timely fashion. This can be done via a letter form the DSMB Chair/Administrator to the PI (or Coordinating Center) for distribution to local IRBs. This letter from the DSMB

should also note whether serious adverse events (SAEs) were discussed, whether they appeared to be related to the trial, and whether the trial was approved to continue.

In phase I and II trials, a number of factors influence risk. A phase I trial or a new intervention (e.g., novel psychosocial treatment, drug or other somatic treatment) may involve increasing risk to a small number of participants as the intervention is escalated in intensity or dosage. For phase II trials, there is sometimes information about risks determined from pilot studies or work with normals, but risk may be increased as more participants are involved and the untoward effects may be confounded by the disease process. In clinical trials involving potentially high risks, special populations, blinded and/or multisite designs, investigators must consider additional monitoring and safeguards. Occasionally, phase I or II trials have established formal Data and Safety Monitoring Boards.

For many phase I and phase II trials, however, independent DSMBs may not be necessary or appropriate when the intervention is low risk. In most low risk, small-scale NIMH-supported studies, the Principal Investigator would be expected to perform the monitoring function as part of the general oversight and scientific leadership of the study. Such PIs must comply with prompt reporting of study-related toxicity and any unanticipated problems involving risks to subjects or others. In some instances, the study investigator or the IRB may determine that an independent individual may be needed for monitoring. In studies of small numbers of subjects, untoward effects may more readily become apparent through close monitoring of individual patients, while in larger studies risk may be assessed through statistical comparisons of treatment groups.

All institutions now carrying out an NIMH-funded multi-site phase I or II clinical trial must establish a data monitoring system (Central Reporting Entity – CRE). In accordance with 45 CFR part 46, serious and unexpected adverse events, as well as any other unanticipated problems involving risks to subjects or others, must be reported to the local IRB associated with the trial. If considered related to the trial, such events must also be reported to appropriate institutional officials and the Office for Human Research Projection (OHRP). In multi-site trials, one site may take on this latter responsibility, and report back to other PIs. Local investigators are to report SAEs to their IRB, and any Coordinating Center and/or CRE. If SAEs are considered related to the trial, then they must also be reported to IRBs at other participating sites.

The CRE for a particular trial will submit summary reports of the discussions of serious and unexpected adverse events (as well as any unanticipated problems involving risks to subjects or others) that are found to be related to the trial to the local IRBs associated with the trial, the NIMH Project Officer, the FDA (as appropriate) and OHRP. Each summary report should contain the following information:

> A statement that review of data and outcomes (as appropriate) across all centers took place on a given date.
>
> A summary of the review of the cumulative serious and unexpected adverse events (as well as any other unanticipated problems involving risks to subjects or others) that are related to the trial. This should include such events reported from all participating sites without specific disclosure by treatment arm, unless safety considerations require such disclosure.

The CRE recommendations for modification to the protocol

The frequency of summary reports to NIMH may depend on the nature of the trial. Additional NIH guidance regarding Data and Safety Monitoring and Reporting Adverse Events are found in the NIH Guide for Grants and Contracts Announcements at the following web sites: http://grants.nih.gov/grants/guide/notice-files/not99-107.html and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html.

(14) Research Patient Care Costs

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payers (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payers or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

(15) **Privacy Act**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and, as applicable, P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

The System of Records applicable to this requirement may be accessed at URL: http://www.nimh.nih.gov/grants/privacyact1997.pdf

(16) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider

award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIMH reserves the right to make a single award, multiple awards, or no award at all from this RFP. In addition, the RFP may be amended or canceled as necessary to meet NIMH requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(17) **Small Business Subcontracting Plan**

******* This document is INCLUDED in the "Just In Time" procedures. *******

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan and Attachment 5 to the RFP.

(18) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(19) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Attachment 3 shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal**.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at http://www.sba.gov/size/SIC2NAICSmain.html .

The Department of Commerce website for the annual determination is: http://www.arnet.gov/References/sdbadjustment.htm.

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector for this project is **621**. A total target for SDB

participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes SDB evaluation factor or subfactor that considers the extend to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation – NAICS Industry Subsector 621

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value - $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractor	15%	$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specified contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented from SDB participation by subcontractors.

(20) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the

entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and(2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

(1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

(3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with the regulations.

(21) **Institutional Management of Conflicting Interests**

(1) The designated official(s) must: (i) review all financial disclosures; and (ii) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

i. public disclosure of significant financial interests;
ii. monitoring of research by independent reviewers;
iii. modification of the research plan;
iv. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
v . divestiture of significant financial interests; or
vi. severance of relationships that create actual or potential conflicts of interests.

(2) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (1) of this section, as the Institution deems appropriate.

(22) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (i) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (ii) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(23) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates the following solicitation provisions by reference with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
b. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

c. Order of Precedence - Uniform Contract Format, FAR Clause 52.215-8 (October 1997)
d. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000) FAR Clause 52.222-24, (February 1999)

B. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a. **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the Statement of Work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the CO. Unless the RFP indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best

alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible. If the Principal Investigator proposed for this RFP is committed in excess of 100% of his/her time the proposal must include appropriate explanations.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. Resumes must not exceed two pages.

2. **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Evaluation Factors for Contract Award (Attachment 3).

3. **Additional Technical Proposal Information**

a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by the initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

4. **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

(a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the Statement of Work will be accomplished within this working relationship.

(b) Unique arrangements which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

(c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

(d) Other factors you feel are important and support your proposed research.

(e) Recommendations for changing reporting requirements or other deliverables if such changes would be more compatible with the offeror's proposed schedules.

C. <u>BUSINESS PROPOSAL INSTRUCTIONS</u>

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Cost and Pricing Data**

(a) General Instructions

(1) You must provide the following information on the first page of your pricing proposal:

(i) Solicitation, contract, and/or modification number;
(ii) Name and address of offeror, to include DUNS number;
(iii) Name and telephone number of point of contact;
(iv) Name of contract administration office (if available);
(v) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(vi) Proposed cost; profit or fee; and total;
(vii) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(viii) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(ix) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the CO and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(x) Date of submission; and
(xi) Name, title and signature of authorized representative.

(b) In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

(c) As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

(d) You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed research objective, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries". You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

(e) When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

(f) Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

(g) If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

(h) As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

3. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

(a) Direct Labor

Provide a time-phased (e.g. monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish basis for estimates.

(b) Fringe Benefits

Show fringe benefits as a separate line item. Include the rates(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or organizational guidelines.

(c) Materials and services

Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2, below. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) All Other. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The CO may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

(d) Indirect Costs

Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

(e) Special Equipment

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase of lease, and the basis for pricing.

(f) Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

(g) Other Costs

List all other costs not otherwise included in the categories described above (e.g., special tooling, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

(h) Royalties

If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the CO, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

(i) Facilities Capital Cost of Money (Commercial Organizations, only)

When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

4. **Formats for Submission of Line Item Summaries**

   The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (see Attachment 5 of the RFP). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

   To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at URL: http://rcb.nci.nih.gov/forms/cpi.htm .

5. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the CO or an authorized representative. As later information comes into your possession, it should be submitted promptly to the CO in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

6. By submitting your proposal, you grant the CO or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price. [Note to Offerors of RFPs using "JUST IN TIME" procedures: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.]

7. **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** (FAR Clause 52.215-20 (October 1997)

   a) Exceptions from cost or pricing data.

      (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

         (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting officer.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include –

(a) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price or recent sales in quantities similar to the proposed quantities;

(b) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(c) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the scheduled item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

8. **Total Compensation Plan - Instructions**

********* ***This document is INCLUDED in the "Just In Time" procedures.*** **********

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional

services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN DISCUSSIONS WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

9. **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

10. **Qualifications of the Offeror**

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and, while not a specific weighted evaluation factor, they are inherent in one or more technical evaluation criterion. Also, they may be used to conduct a relative assessment of offerors during the source selection process if the evaluation factors for contract award, in the specific RFP so indicate.

11. **Property, Equipment, Facilities**

(a) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the CO. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes, in addition to the description and estimated cost of each item:

(1) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(2) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(b) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(c) If an offeror intends to use existing Government-owned facilities in the performance of this proposed contract, the following shall be furnished with the offer: (1) Description and value of all Government production and research property which the offeror or his/her anticipated subcontractors propose to use on a rent-free basis and the cognizant Government Contract Number; (2) Written permission of the CO having cognizance of the property for use of that property without charges; (3) Amount of use (in months) to be made of such property, and (4) Amount of rent which would otherwise be charged for such use, computed in accordance with applicable procurement regulations.

(d) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

12. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

13. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

14. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

15. **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

It is the Government's intention to negotiate and award a contract using the incremental funding concepts describe in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse

the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

16. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

(a) Willingness to perform as a subcontractor for specific duties (list duties).
(b) What priority the work will be given and how it will relate to other work.
(c) The amount of time and facilities available to this project.
(d) Information on their cognizant field audit offices.
(e) How rights to publications and patents are to be handled.
(f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research and Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

17. **Representations and Certifications**

One copy of the Representations and Certifications shall be completed and signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. (See Attachment 6 of this RFP.)

ATTACHMENT 5 to STREAMLINED RFP No. NIMH-01-DI-0017

PROPOSAL INTENT RESPONSE SHEET

PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE July 9, 2001. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

[] DO INTEND TO SUBMIT A PROPOSAL

[] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:
_____

TYPED NAME AND TITLE:_____

INSTITUTION:_____

SIGNATURE:_____

TELEPHONE NO.:_____

EMAIL ADDRESS: _____

FAX NO. _____

DATE:_____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)

_____
_____
_____
_____

TO: National Institute of Mental Health
Contracts Management Branch
Attn: Robert D. Barnie
6001 Exec. Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603
FAX (301) 443-0501
Rb245s@nih.gov

ATTACHMENT 6 TO STREAMLINED RFP No. NIMH-01-DI-0017

APPLICABLE RFP REFERENCES

A. The following general clauses and provisions are applicable to this specific RFP depending on your organizational status: Negotiated Cost-Reimbursement Contract with an Educational Institution, Negotiated Cost-Reimbursement Contract with a Non-Profit or, Negotiated Cost-Reimbursement Research and Development Contract. The clauses are located in the file "General Clauses" at URL: http://amb.nci.nih.gov/clauses/clauses.html .

B. The following items are applicable to this specific RFP and are located in the file entitled (except as noted) FORMS, FORMATS AND ATTACHMENTS at: http://ocm.od.nih.gov/contracts/rfps/Forms1.htm .

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

1. Technical Proposal Cover Sheet
2. Summary of Current and Proposed Activities
3. Technical Proposal Cost Information

SUBMIT WITH BUSINESS PROPOSAL:

1. Proposal Summary and Data record, NIH-2043, with every copy of business proposal.
2. Business Proposal Cost Information (Use form entitled “Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours” which is located at http://rcb.nci.nih.gov/appl/rfp/17004/costfrm.htm).
3. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original
4. Representations and Certifications - Negotiated Contract, only one completed and signed copy

OTHER - TO BE SUBMITTED LATER:

1. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, as required by the CO
2. DHHS Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Subcontracting Plan, to be submitted as directed by the CO

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

1. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
2. NIH 2706, Financial Report of Individual Project/Contract, the form with instructions
3. Procurement of Certain Equipment, NIH(RC)-7
4. NIH Women and Minority Policy
5. Protection of Human Subjects Assurance/Identification/Certification/Declaration, OF310
6. NIH Policy for the Inclusion of Children as Participants In Research Involving Human Subjects
7. Research patient Care Costs, NIH(RC)-11
8. Annual Technical Progress Report Format for Each Study
9. NIH Policy for the Inclusion of Children as Participants in Research Involving Human Subjects.
10. Report of Accountable Personal Property (HHS 565)

C. The Sample Contract Format for R&D Cost Reimbursement contracts is located in the file

entitled, RFP FORMS, FORMATS AND ATTACHMENTS at http://ocm.od.nih.gov/contracts/rfps/Forms1.htm . Supplemental information pertaining to Sections G & H of the Sample Contract Format include the following:

1. **Section G, "Contract Administration Data" paragraph entitled "Invoice Submission" is amended to read as follows:**

Invoice Submissions/Contract Financing Request

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9. Invoice/financing requests shall be submitted as follows:

a. An original and two copies to the following designated billing office:

If hand-delivered or delivery Service	If using U.S. Postal Service
Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 6107, MSC 9603 Rockville, Maryland 20852	Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 6107, MSC 9603 Bethesda, Maryland 20892-9603

Inquiries regarding payment of invoices should be directed to the designated billing office (301) 443-2696.

b. At a minimum, the Contractor agrees to include the following information on each invoice:

1. Contractor's name and invoice date,
2. NIMH's Contract number, or other authorization for delivery of property and/or services
3. Description, cost or price, and quantity of property and/or services actually delivered or rendered,
4. Shipping and payment terms,
5. Other substantiating documentation or information as required by the contract (see paragraph G.3.c, "NIMH Supplemental Billing Instructions" below,
6. Name where practicable, title, phone number, and complete mailing address of responsible official to whom payment is to be sent.

c. NIMH Supplemental Billing Instructions

1. The contractor agrees to provide, as applicable, a detailed breakdown on each invoice of the following cost categories:

(a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
(b) Fringe Benefits - Cite rate and amount

(c) Overhead - Cite rate and amount
(d) Materials & Supplies - Include detailed breakdown.
(e) Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate.
(f) Consultant Fees - Identify individuals and amounts.
(g) Subcontracts - Attach subcontractor invoice(s). (Should be in same format and detail as required of the Prime Contractor.) Include COA Letter Number if applicable.
(h) Equipment - Cite authorization and amount.
(i) G&A - Cite rate and amount.
(j) Total Cost
(k) Fee (if applicable)
(l) Total Cost & Fee

Monthly invoices must include the cumulative total expended to date, adjusted (as applicable) to show any amounts suspended or disallowed by the Government.

2) The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

2. **Section G, "Contract Administration Data" the paragraph entitled "Post Award Evaluation of Contractor Performance" is amended to add:**

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web Site for review and comment by completing the registration form that can be obtained at the following address:

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

3. **Section H "Human Subject" is amended to read as follows:**

H. Human Subjects

Research involving human subjects shall not be conducted under this contract until the final protocol has been approved by, both your local Internal Review Board (IRB) and the NIMH, written notice of such approval has been provided by the NIMH Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the Optional Form 310.